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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,937	08/15/2001	Loretta D. Spotila	DRE-0057	7842

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MARLTON, NJ 08053

EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,937

Applicant(s)

SPOTILA, LORETTA D.

Examiner

Diana B. Johannsen

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

FINAL ACTION

1. This action is in response to the Amendment and Reply filed June 26, 2003. Claims 2-4 have been canceled, and claim 1 has been amended. Claim 1 is now pending and under consideration. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph

3. In view of the cancellation of claims 2-4, the rejection of those claims under 35 U.S.C. 112, first paragraph is moot.
4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the Office action of January 30, 2003.

It is first noted that Applicant's amendments limiting claim 1 to human individuals is sufficient to overcome the rejection in part. However, the claim as written still encompasses the detection of any polymorphism in the TNFR2 gene (including any polymorphism of SEQ ID NO: 1) as an indicator of osteoporosis risk.

The response traverses the rejection on the following grounds. The response states that the specification "provides detailed methods for assessing various polymorphisms in the tumor necrosis factor alpha 2 receptor gene, not simply polymorphisms at positions 593, 598 and 620 of exon 10." Applicant argues that the

specification also discloses "detection of polymorphisms in the microsatellite region" of the TNFR2 gene" at, e.g., pages 5-6 and in Example 2. The response urges that "the Examiner's suggestion that the specification is only enabling for steps/reagents for determining the identity of the nucleotides at positions 593, 598 and 620 of exon 10....is incorrect."

Applicant's arguments have been thoroughly considered but are not persuasive. The Office action of January 30, 2003 (at, e.g., page 7) did in fact discuss the microsatellite polymorphisms of pages 5-6; specifically, it was noted in that action that the data of the specification indicated that these polymorphisms were not significantly associated with osteoporosis. The rejection did not in fact assert that one of skill would not be able to detect these polymorphisms, or that the specification failed to enable well-known techniques and methods of polymorphism detection; rather, the claims were rejected because the combined teachings of the specification and of the art indicate that only a few TNFR2 gene polymorphisms are actually associated with osteoporosis risk, while the claims encompass detection of any TNFR2 gene polymorphism as an osteoporosis risk indicator. Instant claim 1 does not merely requires detection of a polymorphism; rather, it requires detection of a polymorphism as an indicator of osteoporosis risk. Accordingly, enablement of the claim requires that an association between the detected polymorphism and osteoporosis actually exist. As indicated in the Office action of January 30, the specification does establish such an association for a few particular polymorphisms, and therefore the claimed method is enabled with respect to those polymorphisms. However, given the established lack of association between

osteoporosis and other known TNFR2 polymorphisms, and the lack of data in either the specification or in the art with respect to other such polymorphisms, it would require undue experimentation to use applicant's invention in a manner reasonably commensurate with present claim 1. Accordingly, this rejection is maintained.

Claim Rejections - 35 USC § 112, second paragraph

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite over the recitation of the limitation "the TNFR2 gene (SEQ ID NO: 1)." This recitation is indefinite because SEQ ID NO: 1 does not in fact correspond to the TNFR2 gene, but to a small portion thereof. Accordingly, it is unclear as to whether the claim is intended to require the TNFR2 gene, or the fragment comprising exon 10 set forth in SEQ ID NO: 1.

Claim 1 is indefinite over the recitation of the limitation "the human individual" because there is insufficient antecedent basis for this recitation in the claims.

Conclusion

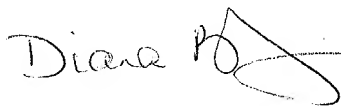
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

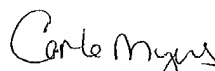
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.



Diana B. Johannsen
September 5, 2003


CARLA J. MYERS
PRIMARY EXAMINER